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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/020,746 02/09/98 ASHKENAZI

HM22/0512

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

05/12/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 2/28/00

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 8-10, 19-29 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☒ Claim(s) 8-10 is/are allowed.
☒ Claim(s) 19-29 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 15
☐ Interview Summary, PTO-413
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Part III: Detailed Office Action

Claims 8-10 and 19-26 are pending and under consideration.

Objections and Rejections under 35 U.S.C. §112:

5 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 19-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 Claims which are drawn to antibodies which bind to proteins having a stated percent identity with the disclosed Apo-2 polypeptide (e.g. claims 19 and 20) or to proteins *comprising* a portion of an Apo-2 polypeptide (e.g. claims 21-24) are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent that these claims are drawn to antibodies which specifically bind to the disclosed Apo-2 polypeptide, no problem exists. However, to the extent that these claims are drawn to variants of Apo-2 or fusions of the Apo-2 polypeptide to other proteins, the claims read on antibodies to epitopes that do not exist in the disclosed Apo-2 polypeptide. For example, an encompassed embodiment of claim 22 would be a
20 fusion protein; giving the claim its broadest reasonable interpretation, antibodies to the heterologous portion of the fusion protein would fall within the metes and bounds of the claim. To the extent that the proteins to which the claimed antibodies bind may comprise unspecified sequences, the metes and bounds of the claims cannot be determined.

25 Claim 22 is additionally indefinite because it is not clear whether it is the extracellular domain which comprises amino acids 54-182, or alternatively whether it is the 'native sequence Apo-2 polypeptide' which is to comprise those amino acids. Claim 24 is similarly indefinite.

Claims 25 and 26 are indefinite for failing to further limit another claim with respect to claim

1, which is canceled.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

5 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10 Claims 19-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies which bind to an Apo-2 polypeptide that consists of the amino acid sequence of SEQ ID NO: 1 or to any portion of SEQ ID NO: 1, does not reasonably provide enablement for antibodies which bind to any protein *comprising* a portion of SEQ ID NO: 1, nor with antibodies which bind to variants having 90-95% identity with SEQ ID NO: 1. The specification does
15 not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

 Claims which are drawn to antibodies which bind to proteins having a stated percent identity with the disclosed Apo-2 polypeptide or to proteins *comprising* a portion of an Apo-2 polypeptide are only enabled to the extent that the claimed antibodies specifically bind to the protein having SEQ
20 ID NO: 1. To the extent that the percentage identity recitation encompasses proteins with novel epitopes, or alternatively to the extent that the *comprising* language of claims 21-24 may encompass epitopes which do not occur in the protein of SEQ ID NO: 1, there is neither adequate written description of the claimed antibodies, nor enablement of how to make or use such antibodies. Without knowing what such antibodies are or to what they bind, it would require undue
25 experimentation to determine how to make or use such.

Advisory Information:

Claims 8-10 are allowable.

30 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office

action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

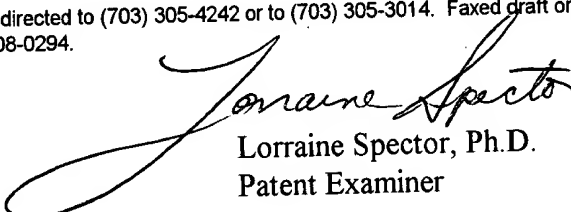
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, Ph.D., can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. Please advise the Examiner at the telephone number above when a fax is being transmitted.

Official papers filed by fax should be directed to (703) 305-4242 or to (703) 305-3014. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.


Lorraine Spector, Ph.D.
Patent Examiner

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